IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

LATHAM & WATKINS LLP 555 Eleventh Street, N.W., Suite 1000 Washington, D.C. 20004, Plaintiff, v. U.S. FOOD AND DRUG ADMINISTRATION 10903 New Hampshire Avenue Silver Spring, MD 20993, Defendant.	Case No.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Latham & Watkins LLP (Latham) brings this complaint for declaratory and injunctive relief, and states as follows in support thereof:

PRELIMINARY STATEMENT

1. The Freedom of Information Act (FOIA), 5 U.S.C. § 552 *et seq.*, "was enacted to promote transparency and accountability in how the federal government discharges its numerous and far-ranging responsibilities." *Shapiro v. U.S. Dep't of Justice*, 153 F. Supp. 3d 253, 256 (D.D.C. 2016). FOIA provides a means for the public to access government documents and "mandates that an agency disclose records upon request, unless they fall within one of nine exemptions." *Id.* at 257. FOIA also recognizes that the government cannot sit on its hands forever; it must make timely determinations regarding what documents it possesses that are responsive to a specific request, and when it will produce them. *See* 5 U.S.C. § 552(a)(6)(A)(i).

2. Defendant Food and Drug Administration (FDA) administers the federal government's food and drug laws, including, as relevant here, the federal framework for new drug approval under the Federal Food, Drug, and Cosmetic Act (FDCA). *See* 21 U.S.C. § 355

3. Within the past year, FDA has approved two drugs using the same active ingredient "amifampridine." *See* News Release, FDA, *FDA approves first treatment for Lambert-Eaton myasthenic syndrome, a rare autoimmune disorder* (Nov. 28, 2018), https://www.fda.gov/news-events/press-announcements/fda-approves/-first-treatment-lambert-eaton-myasthenic-syndrome-rare-autoimmune-disorder; News Release, FDA, *FDA approves first treatment for children with Lambert-Eaton myasthenic syndrome, a rare autoimmune disorder* (May 6, 2019), https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-chlidren-lambert-eaton-myasthenic-syndrome-rare-autoimmune-disorder.

4. The approval of both drugs generated substantial press coverage and public interest. *See* Judy George, *Second Amifampridine OK in LEMS Raises Eyebrows* MEDPAGE TODAY (May 7, 2019), https://www.medpagetoday.com/neurology/generalneurology/79675; Wayne Drash, *FDA undercuts $375,000 drug in surprise move* (May 8, 2019), https://www.cnn.com/2019/05/08/health/fda-firdapse-expensive-drug-surprise-move/index.html. In order to better understand FDA's approvals, on May 16, 2019, Latham filed two FOIA requests with FDA seeking information about new drug applications for drugs containing amifampridine.

5. FDA has not made a determination on Latham's request within the statutorily mandated 20 working days for such determination. 5 U.S.C. § 552(a)(6)(A)(i). Instead, FDA has in fact asked Latham to *withdraw* one of its requests. As a result, FDA is impeding Latham's access to these important records.

6. Administrative remedies under FOIA are deemed exhausted when an agency fails to comply with the statute's applicable time limits for making a determination on a given request. 5 U.S.C. § 552(a)(6)(C)(i). Having fully exhausted applicable administrative remedies for its requests, Latham now turns to this Court to enforce FOIA's guarantee of public access to agency records. Accordingly, Latham asks this Court to declare that FDA has violated FOIA, to order FDA to provide Latham with legally compliant responses to each of its requests, and to grant other appropriate relief, including attorney's fees and costs.

PARTIES

7. Plaintiff Latham & Watkins LLP (Latham) is a private law firm with an office located at 555 Eleventh Street N.W., Suite 1000, Washington, D.C. 20004. Latham submitted the subject FOIA requests as part of its representation of a client and likewise brings suit to further that representation.

8. Defendant FDA is a component of the United States Department of Health and Human Services and an agency of the United States Government within the meaning of 5 U.S.C. § 552(f)(1) and 5 U.S.C. § 552a(a)(1). FDA is headquartered at 10903 New Hampshire Avenue, Silver Spring, MD 20993.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over Latham's claims pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331.

10. This Court has authority to grant declaratory relief pursuant to 28 U.S.C. § 2201.

11. This Court has authority to award injunctive relief pursuant to 5 U.S.C. § 552(a)(4)(B).

12. Venue lies in this district under 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(e).

LEGAL BACKGROUND

13. FOIA "requires the government to disclose, upon request, broad classes of documents identified in 5 U.S.C. § 552(a)," unless the documents are exempt under 5 U.S.C. § 552(b). *See Prison Legal News v. Samuels*, 787 F.3d 1142, 1146 (D.C. Cir. 2015).

14. FOIA imposes strict deadlines on federal agencies when they receive a request for records pursuant to FOIA. First, an agency must acknowledge receipt of a FOIA request, in writing, within ten days of receipt of the request, exclusive of weekends and legal public holidays. 5 U.S.C. § 552(a)(7)(A). By regulation, "[u]pon receipt of a request for records," a division within FDA "shall enter" the request into a public log. 21 C.F.R. § 20.40(c). The regulation provides that "[t]he log shall state," among other things, "the date [the request was] received." *Id.* FDA's public log, however, does not provide the date on which requests were received. *See* FDA FOIA Logs, https://www.fda.gov/regulatory-information/freedom-information/fda-foia-logs (last visited June 6, 2019).

15. Next, an agency must respond to a party making a FOIA request within twenty days of receipt, exclusive of weekends and legal public holidays, notifying that party of the agency's determination whether to fulfill the request and of the requester's right to appeal the agency's determination to the agency head. 5 U.S.C. § 552(a)(6)(A)(i). The D.C. Circuit has explained that to make a valid "determination" under the statute the agency must indicate "the scope of the documents it will produce and the exemptions it will claim with respect to any withheld documents." *Citizens for Responsibility & Ethics in Wash. v. FEC*, 711 F.3d 180, 185-86. 188 (D.C. Cir. 2013) (*CREW*); *see also Seavey v. Dep't of Justice*, 266 F. Supp. 3d 241, 245 (D.D.C. 2017) (the agency must "(1) gather[] and review[] the [requested] documents; (2) determin[e] and communicat[e] the scope of the documents it intends to produce and withhold, and the reasons for withholding any documents; and (3) inform[] the requester that it can appeal

whatever portion of the 'determination' is adverse"). FDA regulations provide that all relevant "time limitations . . . shall begin as of the time at which a request for records is logged" in its public FOIA log, but, as noted *supra*, that log does not contain dates of logging.

16. The agency may extend the statutory twenty-day deadline only in "unusual circumstances," 5 U.S.C. § 552(a)(6)(B)(iii), and must then make the requested records "promptly" available, *id.* § 552(a)(3)(A), (a)(6)(C)(i), except where it can establish that one of FOIA's narrow exemptions listed at § 552(b) applies.

17. When an agency fails to make a timely determination with respect to a perfected FOIA request, a requester is deemed to have exhausted administrative remedies with respect to the request and may immediately file suit in district court. 5 U.S.C. § 552(a)(6)(C); *CREW*, 711 F.3d at 186.

FACTUAL BACKGROUND

18. On May 16, 2019 Latham submitted two FOIA requests to FDA via FedEx as part of its representation of a pharmaceutical client.

19. The first of the two requests sought copies of all records associated with any Investigational New Drug Applications and New Drug Applications for any drug containing "amifampridine" (the Amifampridine Request). *See* Exhibit A, attached. Latham agreed to pay all necessary fees for this request.

20. The second of the two requests sought copies of all records associated with two specific Investigational New Drug Applications and New Drug Applications submitted for one amifampridine-based drug manufactured by Jacobus Pharmaceutical Company (Ruzurgi) and another amifampridine-based drug manufactured by Catalyst Pharmaceuticals Inc. (Firdapse) (the Ruzurgi/Firdapse Request). *See* Exhibit B, attached. Latham agreed to pay all necessary fees for this request.

21. Both the Amifampridine and Ruzurgi/Firdapse Requests were delivered to FDA on May 17, 2019. FDA sent letters to Latham dated May 20, 2019, acknowledging receipt of both requests. *See* Exhibit C, attached (acknowledging receipt of Amifampridine Request); Exhibit D, attached (acknowledging receipt of Ruzurgi/Firdapse Request). The acknowledgement letters, however, do not indicate the date that each request was in *fact* received.

22. FDA also entered the Amifampridine and Ruzurgi/Firdapse requests in its public FOIA log. The public log likewise does not provide a date of receipt.

23. Because FDA's acknowledgement letters were dated May 20, 2019, that is the latest plausible date that it could be in receipt of the Amifampridine and Ruzurgi/Firdapse Requests. Accordingly, FDA was required to make the statutorily mandated determination on the two requests by June 18, 2019.

24. On May 24, 2019, a representative from FDA's Center for Drug Evaluation and Research telephonically requested that Latham withdraw the Amifampridine Request in full, and that production could be expensive ("tens of thousands of dollars") and time-consuming (production may not be complete for "at least two years"). Latham did not agree to withdraw this request.

25. As of the date of this filing, FDA has not made a determination within the meaning of FOIA on either the Amifampridine Request or the Ruzurgi/Firdapse Request.

26. As of the date of this filing, FDA has made available documents related to the Ruzurgi/Firdapse Request on its website Drugs@FDA. See FDA, Drug Approval Package: Ruzurgi, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/209321Orig1s000TOC.cfm (last accessed June 25, 2019. These documents were not available on May 16, 2019, when Latham

submitted the Ruzurgi/Firdapse Request to FDA, and FDA may consider them to be part of their response to the Ruzurgi/Firdapse Request. However, these documents are not a complete response to the Ruzurgi/Firdapse Request.

27. Because the FDA has not issued a determination within the statutorily mandated timeframe, Latham is deemed to have exhausted its administrative remedies. 5 U.S.C. § 552(a)(6)(C); *CREW*, 711 F.3d at 186.

CLAIMS FOR RELIEF

CLAIM I
(Failure to Produce Records)

28. The foregoing paragraphs are incorporated by reference as if set forth in full herein.

29. FOIA requires agencies to make a determination regarding all requests within 20 working days, or 30 days where unusual circumstances are present and the agency sends a timely written notice of such circumstances.

30. Latham submitted its perfected Amifampridine and Ruzurgi/Firdapse Requests to FDA, which the agency received *no less than* 20 days ago (exclusive of weekends and legal public holidays). *See* Exhibits C, D.

31. Latham has a statutory right to receive a determination from FDA as to the Amifampridine and Ruzurgi/Firdapse Requests within the time frames that Congress required through FOIA.

32. FDA violated FOIA by failing to make the required determinations in response to Latham's Amifampridine and Ruzurgi/Firdapse Requests, and by failing to produce records in response to Latham's Requests.

33. Latham is being harmed by reason of FDA's violation of FOIA and its unlawful withholding of records to which Latham is entitled. Latham will continue to be harmed unless FDA is compelled to comply with the statute and produce the requested records.

CLAIM II
(Costs and Fees)

34. The foregoing paragraphs are incorporated by reference as if set forth in full herein.

35. Pursuant to 5 U.S.C. § 552(a)(4)(E), "[t]he court may assess against the United States reasonable attorney fees and other litigation costs reasonably incurred in any case under this section in which the complainant has substantially prevailed."

36. Latham is statutorily entitled to recover fees and costs incurred as a result of FDA's failure to make timely determinations with regard to the Amifampridine and Ruzurgi/Firdapse Requests. 5 U.S.C. § 552(a)(4)(E)(i); *Baker & Hostetler LLP v. U.S. Dep't of Commerce*, 473 F.3d 312, 324 (D.C. Cir. 2006) (complainant law firm is an organizational litigant statutorily eligible for costs and attorney's fees).

37. Latham asks the court to order FDA to pay reasonable attorney fees and other litigation costs incurred in this case.

REQUEST FOR RELIEF

WHEREFORE, Latham respectfully requests that this Court enter judgment in its favor and prays for the following relief:

1. A declaration pursuant to 28 U.S.C. § 2201 that FDA has violated the Freedom of Information Act by failing to lawfully satisfy Latham's Amifampridine and Ruzurgi/Firdapse Requests.

2. An order enjoining FDA to:

a. Respond to Latham's Amifampridine and Ruzurgi/Firdapse Requests; and

b. Release immediately all responsive records to Latham's Amifampridine and Ruzurgi/Firdapse Requests.

3. An order awarding Latham its costs and attorney's fees.

4. Such other and further relief as the court deems just and proper.

Dated: June 25, 2019

Respectfully submitted,

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